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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,298	11/21/2001	Alan D. Schreiber	555-63	9500

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/989,298	SCHREIBER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *4*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *5-10*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ADVISORY ACTION

The amendment and response filed on 7-27-2004 are acknowledged. Claims 1-2, 11-25 have been canceled. Claims 4-10 are pending and currently under examination.

Claim Objections Withdrawn

The objection to the specification for failing to properly label the Brief Description of Drawings section is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5-10 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "cytoplasmic domain modified to comprise at least one L-T-L peptide" is maintained for reasons of record.

Applicant argues:

1. Claim 5 is drawn to a method of enhancing the ability of a cell to degrade a particle. The method comprises method comprises introducing into the cell a nucleic acid sequence encoding an Fc receptor comprising and L-T-L sequence in a cytoplasmic domain thereof.

2. The claim requires that the Fc receptor comprise a γ chain cytoplasmic domain modified to comprise at least one L-T-L peptide.

3. The required γ chain cytoplasmic domain does not inherently possess an L-T-L motif.

4. Paul's "Fundamental Immunology" textbook clearly demonstrates that FcγRII does not contain a γ chain.

Applicant's arguments have been fully considered and are deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain. Consequently, Applicant's arguments are not germane and hence are non-persuasive.

As outlined previously, Claim 5 is rendered vague and indefinite by the use of the phrase "cytoplasmic domain modified to comprise at least one L-T-L peptide". It is unclear why said domain would have to be modified since it inherently possesses one L-T-L motif. As written, it is impossible to determine the metes and bounds of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 5,776,910 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) for the reasons set forth in the previous Office action in the rejection of claims 5-10 and 22. The cancellation of claim 22 has rendered the rejection of said claim moot.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 4-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9).

Applicant argues:

1. Claim 5 requires an Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L.

2. The cited patent makes no mention of an L-T-L sequence nor does it suggest L-T-L sequences in the claimed environments. Downey et al. in no way alters this fact.

Applicant's arguments have been fully considered and are deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain.

Therefore, as outlined previously, U.S. Patent No. 5,776,910 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 7-9). Said Fc receptor can be an FcγRIIA receptor (claims 1, 14-15 and 17). Moreover, said cells may be normally phagocytic, i.e. normally express FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express FcγRIIA (claims 5-6) It should be noted that the U.S. Patent 5,776,910 does not recite that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed in U.S. Patent 5,776,910 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see Downey et al. page28441-28442). Finally, while methods recited in U.S. Patent 5,776,910 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

Claims 5-10 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 6,068,983 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) for the reasons set forth in the previous Office action in the rejection of claims 3-10 and 22.

Applicant argues:

1. Claim 5 requires an Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L.

2. The cited patent makes no mention of an L-T-L sequence nor does it suggest L-T-L sequences in the claimed environments. Downey et al. in no way alters this fact.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain.

Therefore, as outlined previously, U.S. Patent No. 6,068,983 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 9-11). Moreover, said cells may be normally phagocytic, i.e. normally express Fc receptors, i.e.

FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express Fc receptors, i.e. FcγRIIA (claims 5-6, 8) It should be noted that the U.S. Patent 6,068,983 does not recite that the claimed Fc receptor is FcγRIIA or that said receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif) and FcγRIIA is encompassed by the broadly recited genus of Fc receptors. Moreover, while the methods disclosed in U.S. Patent 6,068,983 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for an Fc receptor, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see Downey et al. pages 28441-28442). Finally, while methods recited in U.S. Patent 6,068,983 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6) is maintained for the reasons set forth in the previous Office action.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5) into said cells wherein said cells do not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9).

Applicant argues:

1. Downey et al. neither teaches nor suggests modifying a γ chain cytoplasmic domain to include an L-T-L motif) as required by the instant claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain.

Therefore, as outlined previously, Downey et al. disclose methods for transfecting FcγRIIA into non-myloid cells (see page 28437). Said methods conferring on said cells not only particle internalization (phagocytosis) but also phagosomal maturation and acidification. Said phagolysosomes were further disclosed to limit the growth of internalized microorganisms (see pages 28441-28442). It should be noted that Downey et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif).

The rejection of claims 5-8 and 10 under 35 U.S.C. 102(b) as being anticipated by Schreiber et al. (U.S. Patent No. 5,776,910) for the reasons set forth in the previous Office action.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Applicant argues:

1. Schreiber et al. is silent with regard to an L-T-L sequence and in no way teaches (inherently or explicitly), modifying a γ chain cytoplasmic domain to include an L-T-L motif) as required by the instant claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain.

Therefore, as outlined previously, Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al. further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines 24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

The rejection of claims 5-8 and 10 under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (U.S. Patent No. 6,068,983) for the reasons set forth in the previous Office action.

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Applicant argues:

1. The cited reference says nothing of L-T-L sequences and cannot be viewed as teaching or suggesting modification of a γ chain cytoplasmic chain so as to include an L-T-L motif as required by the instant claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Fc receptor comprising a γ chain cytoplasmic domain modified to include at least one L-T-L) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to Fc receptors comprising an L-T-L sequence in a cytoplasmic domain.

Therefore, as reiterated above, FcγRIIA inherently possesses a L-T-L sequence (motif) in its cytoplasmic domain. Consequently, Downey anticipates the instant invention since the rejected claims read on methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding an FcγRIIA receptor comprising a single L-T-L peptide sequence in its cytoplasmic domain.

As outlined previously, Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al. further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines 24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

Conclusion

Claim 4 is allowed.

Claims 6-10 would be allowable if they were amended to depend only on claim 4.

Claims 5-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
September 2, 2004

L. F. Smith

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